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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,002	10/30/2000	George M. Johnson	BQD-003.01	7813

27581 7590 07/31/2002

MEDTRONIC, INC.
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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/31/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/702.002

Applicant(s)

JOHNSON ET AL.

Examiner

Nikita R Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7,8,11,12 6) ☐ Other: ____

DETAILED ACTION

Inventorship

1. In view of the papers No. 9 and 10 filed on January 08, 2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48 (a). The inventorship of this application has been changed by deleting the inventor's named Gerard Von Hoffmann (see paper # 10) and correcting the named inventors (see paper # 9). The correct inventors in this application are George M. Johnson, John T. Kilcoyne, Ross Tsukashima, Matthew T. Yurek, Scott Harris, and adding the inventor's name Philip J. Simpson.
2. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-11, 14-16, 19, 20, 22, 23, 27, 28, 30, 32 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Silverman et al. ('063) cited by Applicant. Silverman et al. ('063) teach a method of implanting a bulking device beneath mucosa in the lower esophagus comprising the steps of: puncturing the mucosa with a device having a first cross sectional area (see Figure 2); creating a pocket beneath the mucosa by introducing a volume of fluid, wherein the fluid comprises saline or contrast media (see column 11, lines 10-29) within the range of from about 0.5 cc to about 5 cc of fluid beneath the mucosa (see column 15, lines 33-39), wherein the introducing a volume of fluid is accomplished using an

injection needle, wherein the needle is within the range of from about 18 gauge to about 30 gauge (see column 5, lines 16-21), and in communication with the puncture; enlarging the puncture; and introducing a hydrogel, which is inherently expandable in response to exposure to fluid, bulking device (see column 9, lines 54-66) through the puncture and into the pocket (see Figures 7 and 8; column 15, lines 23-39), wherein the bulking device is expandable from an introduction cross sectional area to an enlarged cross sectional area, and the introduction cross sectional area is greater than the first cross sectional area (see figures 7 and 8; and column 19, lines 31-34). Further, Silverman et al. ('063) teach a method of implanting the bulking device, wherein the puncture enlarging step comprises introducing a dilator (balloon) through the puncture (see column 19, lines 31-34); and advancing a tube through the enlarged puncture and introducing the bulking device through the tube (see column 4, lines 21-31). Also, Silverman et al. ('063) teach a method of removing the bulking device from the pocket, which is accomplished by creating (establishing) a passageway through tissue (mucosa) to the bulking device, by introducing a solvent DMSO to dissolve the bulking device, by using a sharpened instrument (needle) (see column 19, lines 20-34); by using an endoscope (see column 4, lines 17-30). A step of locating the bulking device is an inherent step of the method of explanting said bulking device.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17, 18, 21, 24-26, 29, 31 and 33 are rejected under 35

U.S.C. 103(a) as being unpatentable over Silverman et al. ('063) cited by

Applicant as applied to claims 14, 15, 19, 20 and 27 above. With regard to

claims 17 and 18 Silverman et al. ('063) teach methods of implanting and

explanting a bulking device beneath mucosa in the lower esophagus, as

described in paragraph 5 above, but they do not teach a method of implanting a

bulking device, wherein the bulking device has a diameter prior to implantation

within the range of from about 0.2 mm to about 5 mm, and has a cross section

prior to implantation of no more than about 2.5 mm. It would have been obvious

to one of ordinary skill in the art at the time of the invention to determine through

routine experimentation an appropriate diameter and cross section for

implementing the bulking device prior to implantation within the range of

diameters and cross sections Applicant provides in the claims. With regard to

claims 21, 24-26, 29 and 31-33 Silverman et al. ('063) teach methods of

implanting and explanting a bulking device beneath mucosa in the lower

esophagus, as described in paragraph 5 above, but they do not teach a method

of explanting or removing the bulking device using suction, utilizing a laser, using

Art Unit: 3736

an energy source, cutting the bulking device into pieces, using a mechanical explanting tool, using an RF electrode, pushing the bulking device through the passage. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use suction, a laser, a energy source, cutting, a mechanical explanting tool, an RF electrode, or pushing the bulking device through the passage for the solvent-based extraction of Silverman et al ('063), since it has generally been held to be within the skill level of the art to substitute alternative ways for explanting implants from the tissues or organs.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. ('063) cited by Applicant as applied to claims 1 and 11 above, in view of Schiff (US 4,473,067). Silverman et al. ('063) teach methods of implanting and explanting a bulking device beneath mucosa in the lower esophagus, as described in paragraph 5 above, but they do not teach a method of implanting a bulking device, wherein the dilator removably carries an introducer sheath, and the steps of removing the dilator from the introducer sheath and introducing the bulking device through the introducer sheath and into the pocket. However, Schiff ('067) teaches a dilator (balloon catheter) inserted into an introducer sheath (see abstract and Figure 5), steps of introducing the sheath with the dilator into the body of the patient (see column 2, lines 26-31), and steps of removing the dilator from the introducer sheath, wherein the portion of the sheath within the artery simplifies removal of the dilator (balloon) through the sheath rather than pulling the dilator (balloon catheter) (see column 2, lines

Art Unit: 3736

26-31 and column 6, lines 6-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method steps of Silverman et al. ('063) by including an introducer sheath as taught by Schiff ('067), since Schiff ('067) teaches an introducer sheath, which simplifies removal of the dilator (balloon) through the sheath rather than pulling the dilator (balloon catheter).

Conclusion

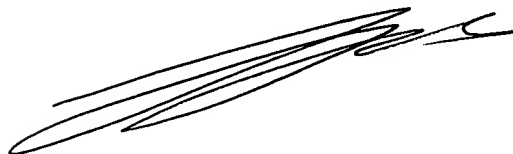
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bacich et al. ('889); Kaplan et al. ('563); Murphy-Chutorian et al. ('577); Winkler A.R., McClenathan D.T., Borger J.A., Ahmed N. "Retrograde esophagoscopy for foreign body removal". May 1989; Journal of Pediatric Gastroenterology and Nutrition; 8(4); pp 536-40 (Abstract only), and Bertoni G, Pacchione D, Sassatelli R., Ricci E., Mortilla M.G., Gumina C. "A new protector device for safe endoscopic removal of sharp gastroesophageal foreign bodies in infants", May 1993; J Pediat Gastroent Nutr; 1(4); pp 393-6 (Abstract only).

Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

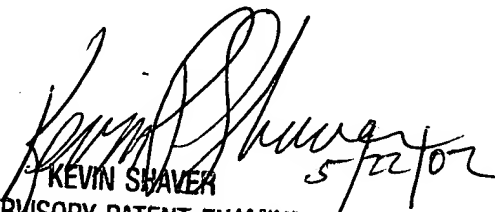
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric F Winakur can be reached on (703) 308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Nikita R Veniaminov
Examiner
Art Unit 3736

April 26, 2002



KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
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5/22/02